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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,679	08/18/2003	Xavier Paliard	PP01612.009 (2300-1612.10	4593

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,679	PALIARD ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/30/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8,23-33,37-40 and 42* is/are pending in the application.

4a) Of the above claim(s) *23-33,37-40 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 2-6, 8, 23-33, 37-40 and 42 are pending.

Response to Amendment

This is a response to the amendment filed 09/23/05. Claims 1, 7, 9-22, 34-36, 41 and 43-44 have been canceled. Claims 23-33, 37-40, 42 were withdrawn from the consideration. Claims 2-6 and 8 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

I n the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The rejoinder will be considered until an elected product claim is found allowable.

Double Patenting

1. Claim 2 is still provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41-44 of copending Application No. 10,612,884. Applicants admitted that the official terminal disclaimer will be filed over this double patenting issue until there is indication there is an allowable subject matter in the present application. Therefore, the rejection is still maintained.

Claim Rejections - 35 USC § 102

2. Claim 2 is still rejected under 35 U.S.C. 102(b) as being anticipated by Grakoui et al. (J. Virol. 1996, Vol. 67, No. 2, pp. 1385-1395) or Selby et al. (J. Gene. Virol. 1993, Vol. 74, pp. 1103-1113) under the same ground as stated in the previous Office Action.

3. Applicants argue that Grakoui et al. or Selby et al. do not teach the claimed invention since the Grakoui et al. fails to disclose that the polypeptide lacks the E1, E2, P7 and NS2 and it only contains core, NS3, NS4, NS5a and NS5b antigen fragments.

4. Applicants' argument has been fully considered; however, it is not found persuasive. The claimed the polypeptide is not considered to contain only core, NS3, NS4, NS5a and NS5b polypeptides, it may comprise other fragment of HCV polyprotein because the citation of "consisting essential of" used in the claim is still considered to be an open language. Therefore, the reference by Grakoui et al. or Selby et al. still anticipates the claim.

5. Claim 2 is still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office action as being anticipated by Cheng et al. (Clinical and Diagnostic Virology 1996, Vol. 6, Issues 2-3, pp. 137-145).

6. Applicants traverse the rejection and submit that the NS5 disclosed by Cheng et al only contain 1-73 amino acids disclosed by Maeno et al., which does not contain the fragment of NS5b of the claimed polypeptide in the instant claim.

7. Applicants' argument has been fully considered; however, it is not found to be persuasive to overcome the rejection because there is no indication in Maeno's reference that fragment of NS5 used by Cheng et al. contains the amino acid residues from 1 to 73 of NS5. Therefore, the claim is still anticipated by the cited reference.

New ground Objection and Rejections:

Claims objection

8. Claims 3-5 are objected to because of the following informalities: it depends on the canceled claim 1. Appropriate correction is required.

9.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claims 3-5 are vague and indefinite because they fail to define what the claimed polypeptide structures are since they depend on a non-existing claim.

13. Claims 3and 4 are also vague in that the use of a relative term of "derived". Since the specification does not provide a standard for ascertaining the requisite degree of derivation and the term of "derivation" has many interpretations, one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Therefore the claim is considered as indefinite.

14. Claims 2 and 8 are rejected under 35 U.S.C. 1 12, second paragraph, which applicant regards as the invention. The claims read on a fusion peptide or compositions comprising either a

fusion protein consisting essentially of polypeptides from the core, NS3, NS4, NS5w and NS5b regions of the HCV polyprotein. It is unclear from the claims what is included or excluded by the use of the language "consisting essentially of ' in this instance. In particular, while it appears that the claim exclude the inclusion of polypeptides from other HCV polypeptides than those disclosed in the claims, however, the open language is not clear if the claims are intended to exclude the presence of other polypeptides from the claimed fusion proteins. Because it is not clear what does it meant by the claim language, the claims are rejected as being indefinite.

15. For the purposes of the action, the claims are treated as though they read on fusion proteins or polypeptide combinations that may include multiple polypeptides from the indicated HCV polypeptides. 1.e., the claims are read to include fusion proteins that may contains multiple copies of the same epitope from an HCV polypeptide, multiple polypeptides representing different epitopes from the same HCV polypeptide, and multiple polypeptides representing different versions of the same epitope from different HCV isolates or strains.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 2 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al. (WO 91/15771A1).

18. Houghton et al. teach that serological studies on HCV antigens that confirmed that no single HCV polypeptide is so identical that is immunological reactive with all sera. Therefore, the assay for detecting HCV should include 1st antigen from the C domain and at least additional HC antigenic domain selected from the group consisting of NS3, NS4m, NS5. They further teaches that a NS5 antigenic peptide including NS5a and NS5b region (See lines 7-32 on page 3 and lines 20-26 on page 21). Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

20. Claim 2 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Houghton et al. (US patent No. 5, 683,864A).

21. The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

22. Houghton et al. teach that serological studies on HCV antigens that confirmed that no single HCV polypeptide is so identical that is immunological reactive with all sera. Therefore, the assay for detecting HCV should include 1st antigen from the C domain and at least additional HC antigenic domain selected from the group consisting of NS3, NS4m, NS5. They further teaches that a NS5 antigenic peptide including NS5a and NS5b region (See lines 18-24 on column 5, claims 1-1, 16 and example 5). Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton et al. (WO 91/15771A1) and Valenzuela et al. (WO 97/44467).

25. Houghton et al. teach that serological studies on HCV antigens that confirmed that no single HCV polypeptide is so identical that is immunological reactive with all sera. Therefore, the assay for detecting HCV should include 1st antigen from the C domain and at least additional HC antigenic domain selected from the group consisting of NS3, NS4m, NS5. They further teaches that a NS5 antigenic peptide including NS5a and NS5b region. They did not explicitly teach that the antigen peptides should selected from different strain of the virus.

26. Valenzuela et al. disclose a HCV fusion peptide comprising multiple copy epitope sequence having a general structural formulation (A)x-(B)x-(C)z, wherein the A, B and C are different each from other and contains at least 5 and not more than 100 amino acids, wherein y is 2 or more and x and z are each independently integers selected from 1 or more. Moreover, A, B and C are different antigen peptides selected from different regions of HCV like NS3, NS4, NS5, C100, C25, core, E1, E2, c33c, c100-3 and c22. While Valenzuela et al. do not teach each of the peptide being in the fusion protein is derived from a different strain of HCV, they teach that any given organism varies from one individual organism to another and further that a given organism such as virus can have a number of different strains. For example, numerous HIV isolates exist and hepatitis C virus including at least strains 1, 2, 3. Each of these strains will include equivalent antigenic determinations. More specifically, each strain will include a number of antigenic determinations that will be present on all strains of the virus but will slightly different from one viral stain to another. For example, hepatitis C includes the antigen determinant in NS3 region appears in three different forms on the three different viral strains. Therefore, a highly

sensitive and selective immunoassay can be produced using the multiple epitope fusion antigens (page 10, lines 5-8) or multiple cope epitope of same epitope or equivalent antigenic determinants (lines 9-17 on page 13, and Fig. 1).

27. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references and to combine the method taught by Houghton et al. and Valenzuela et al. in order to improve the selectivity and sensitivity of an antigen fusion peptide for detecting a biological sample that is possibly infected with any variable strain of HCV to make a fusion peptide antigen comprising different antigenic epitopes from different regions of HCV virus of an antigenic fusion peptide with different antigenic epeitoes selected from different regions of different virus serotypes. Hence the claimed invention as a whole is prima facie obvious absence unexpected result.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAOQUN LI, MD
PATENT EXAMINER

Bao Qun Li
12/01/2005.